UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

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TAMARA CARTER and DAVID CARTER, Plaintiffs, v. JOHNSON & JOHNSON; ETHICON, INC.; and ETHICON LLC, Defendants.	Case No. 2:20-cv-001232-KJD-VCF ORDER

Presently before the Court is Defendant's Motion to Exclude Peggy Pence, PH.D. (#194). Plaintiffs filed a response in opposition (#200) to which Defendant replied (#214).

I. Factual and Procedural Background

This is a products liability action involving two prescription medical devices– Prolift and TVT. On July 23, 2010, at St. Rose Dominican Hospital in Las Vegas, Nevada, Dr. Gregory Hsieh implanted a Prolift device for Plaintiff Tamara Carter's ("Mrs. Carter") posterior pelvic prolapse and a TVT mid-urethral sling for Mrs. Carter's stress urinary incontinence ("SUI"). Mrs. Carter alleges that these medical devices caused her injuries, and that Defendants are liable under claims of strict liability for failure to warn and for design defect. Her husband, Plaintiff David Carter ("Mr. Carter") raises a loss of consortium claim. Additionally, Plaintiffs claim that Defendants' conduct was malicious, oppressive, willful, wanton, reckless, and grossly negligent. Defendants ("Ethicon") deny Plaintiffs' allegations and assert that Prolift and TVT were state of the art at the time of implant, that Mrs. Carter's alleged injuries pre-dated her surgery, that Mrs. Carter assumed the risks, and that Mrs. Carter's own actions contributed to her injuries.

Peggy Pence, Ph.D., RAC, FRAPS is a Ph.D. toxicologist, scientist, and pharmaceutical and medical device product development, clinical studies, and regulatory affairs specialist. She

has decades of experience in the medical device and pharmaceutical industries, has received numerous regulatory professional accolades, and has extensive toxicology, pharmacology, and continuing regulatory education and training. She has earned peer-reviewed certification of the Regulatory Affairs Professional Society ("RAPS"), based on her professional experience, credentials, and training. Beyond being RAPS certified, Dr. Pence is also a RAPS Fellow.

Dr. Pence seeks to apply her extensive experience to assist the jury in understanding the regulatory requirements and industry practices that form the standard of care for a reasonable medical device manufacturer with regard to testing, labeling and post-market vigilance. Defendants object to her certification as an expert based on a non-binding opinion from a different district court. Defendant also seeks to exclude each of Pence's specific opinions.

II. Analysis

A. Legal Standard

Federal Rule of Evidence ("Rule") 702 permits a "witness who is qualified as an expert by knowledge, skill, experience, training, or education [to] testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case." The Supreme Court gave expanded direction on Rule 702 in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). In Daubert, the Court held that Rule 702 imposed "a special obligation upon a trial judge to 'ensure that any and all scientific testimony… is not only relevant, but reliable.'" See Kumho Tire Co. v. Carmichael, 526 U.S. 137 (1999). The Court expanded this gatekeeping obligation to all expert testimony. Id. at 147. Daubert "established that, faced with a proffer of expert scientific testimony, the trial judge, in making the initial determination whether to admit the evidence, must determine whether the expert's testimony reflects (1) "scientific knowledge," and (2) will assist the trier of fact to understand or determine a material fact at issue." Daubert, 509 U.S. at 592. The "focus must be solely on principles and methodology, not on the conclusions that they generate." Id. at 595.

The Ninth Circuit has emphasized that "Rule 702 is applied consistent with the liberal thrust of the Federal Rules and their general approach of relaxing the traditional barrier to opinion testimony." Jinro Am. Inc. v. Secure Investments, Inc., 266 F.3d 993, 1004 (9th Cir. 2001). "An expert witness–unlike other witnesses–is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation, so long as the expert's opinion [has] a reliable basis in the knowledge and experience of his discipline." Id. (citations and quotation marks omitted).

In Daubert, the Court also clarified that parties should not be "overly pessimistic about the capabilities of the jury and of the adversary system generally." Daubert, 509 U.S. at 596. "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." Id. "The role of the Court is not to determine 'the correctness of the expert's conclusions but the soundness of his methodology.'" Great W. Air, LLC v. Cirrus Design Corporation, No. 2:16-CV-02656-JAD-EJY, 2019 WL 6529046, *3 (D. Nev. 2019). "The judge is supposed to screen the jury from unreliable nonsense opinions… [t]he district court is not tasked with deciding whether the expert is right or wrong, just whether his testimony has substance such that it would be helpful to a jury." Id. at 4.

B. Peggy Pence, Ph.D. Qualification

While it is true that Dr. Pence is not a doctor or biomedical engineer, she has more than forty years of experience in the research and development of pharmaceuticals and medical devices. She founded and presides over a company that provides "advice, guidance, and product development services to pharmaceutical/biopharmaceutical and medical device companies in the areas of strategic planning, preclinical testing, clinical trials design and conduct, and regulatory matters involving the U.S. Food and Drug Administration (FDA)[.]" Pence has "designed clinical trials for diseases of the female genital system and [has] been involved in both preclinical and/or clinical testing of novel medical devices and biologics for wound healing applications, including both deep wounds and surgical incisions." The MDL Court also found that she had enough "accumulated knowledge about the content of product labeling" to testify,

especially considering her "medical and scientific literature" review, her study of the "relevant IFUs" and consideration of "internal Ethicon documents[.]" In re Ethicon Inc., Pelvic Repair Sys. Prod. Liability Litig., 2017 WL 989714 *2-3 (S.D. W. Va. March 10, 2017). Accordingly, the Court denies Defendant's motion to exclude Pence is denied.

C. Motion to Exclude Pence's Pre-marketing Testing Opinion as Unreliable

Originally, the MDL court ruled that Pence's opinion on pre-marketing testing was unreliable because it was made "in [her] professional opinion" without a clear explanation of which standards or authorities required more adequate testing. In re Ethicon Inc., Pelvic Repair Sys. Prod. Liability Litig., 2014 WL 186872 *18 (S.D. W. Va. January 15, 2014). Since then Pence clarified her opinion "clearly demonstrate[ing] hat her methodology and opinions were not based upon her 'professional opinion' alone" and instead arose from her review of a "voluminous amount of peer-reviewed scientific articles, data, government codes and regulation, deposition testimony provided in this litigation, and internal documents[.]" Sanchez v. Boston Scientific Corp., 2014 WL 4851989 *33 (S.D. W. Va. September 29, 2014) (internal quotations omitted). Like Judge Goodwin in Sanchez, the Court is convinced that Dr. Pence has adequately bolstered her expert report by citing to "multiple sources that stress the importance of running clinical trials before incorporating mesh materials into a surgical product." Id. at 34 (listing studies and recommendations of government and professional organizations recommending more clinical trials). Accordingly, the Court denies Defendant's motion to exclude Pence's pre-marketing testing opinion as unreliable.

D. Motion to Exclude Pence's Opinion #2 with respect to Warnings

Defendant asserts that Pence applies the wrong legal standard because she fails to take into account what was already known by the physicians to be warned. A manufacturer satisfies its duty to warn the end user of its product's potential risks by providing an adequate warning to a learned intermediary—here, pelvic floor surgeons. See Fisher v. Prof'l Compounding Centers of Am., Inc., 311 F. Supp. 2d 1008, 1021 (D. Nev. 2004); Phillips v. C.R. Bard, Inc., No. 3:12-cv-00344-RCJ-WGC, 2014 WL 7177256, at *9 (D. Nev. Dec. 16, 2014). There is no duty to warn pelvic floor surgeons of a risk that is commonly known by them. See General Elec. Co. v.

Bush, 88 Nev. 360, 365 (1972) ("Warning need not be given against dangers which are generally known") (citing Helene Curtis Industries, Inc. v. Pruitt, 385 F.2d 841, 858 (5th Cir. 1967)). Thus, Nevada's adherence to the learned intermediary doctrine requires an assessment of what physicians already know. Defendant asserts that Pence fails to make that assessment.

However, Pence clearly makes an evaluation of what doctors knew about the risks. She relied on the testimony of Dr. Chen, the internal documents from Ethicon, the depositions of physicians trained in the surgical treatment of SUI and the use of TVT-O, and adverse events in medical literature. Therefore, the Court finds that Pence has not failed to apply the wrong legal standard and has used a sound methodology to arrive at her opinion. That opinion may be "shaky" but "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." Daubert, 509 U.S. at 596. Defendant's motion to exclude this opinion is denied.

E. Exclusion of the terms "misbranded" and "adulterated"

Defendant seeks to exclude use of the terms misbranded and adulterated because they are legal conclusions. Defendant correctly asserts that the terms are defined under 21 U.S.C. § 351 and 352. The use of these terms relate to opinions regarding FDA regulations and requirements. The Court grants the motion to exclude use of these terms and references to the alleged violations of FDA regulations and requirements, because they are not helpful to the jury and are potentially misleading. Therefore, the Court grants the motion to exclude use of these terms.

III. Analysis

Accordingly, IT IS HEREBY ORDERED that Defendant's Motion to Exclude Peggy Pence, PH.D. (#194) is **GRANTED in part and DENIED in part.**

DATED this 30th day of September 2022.

Kent J. Dawson
United States District Judge